DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services
Center for Substance Abuse Treatment
Center for Substance Abuse Prevention

Guidance for Applicants (GFA) No. SM 03-001
Part I - Programmatic Guidance

Long Title: Targeted Capacity Expansion Grants to Enhance State Capacity for Emergency Mental Health and Substance Abuse Response

Short Title: State Emergency Response Capacity

Application Due Date: October 22, 2002

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Catalog of Federal Domestic Assistance (CFDA) No. 93.243 Authority: Section 520A, Section 509, and Section 516 of the Public Health Service Act, as amended and subject to the availability of funds. This program is being announced prior to the full annual appropriation for Fiscal Year (FY) 2003 for the Substance Abuse and Mental Health Services Administration's (SAMHSA) programs. Applications are invited based on an assumption that sufficient funds will be appropriated for FY 2003 to permit funding of a reasonable number of applications being hereby solicited. This program is being announced in order to allow applicants sufficient time to plan and prepare applications. Solicitation of applications in advance of a final appropriation will also enable the award of appropriated grant funds in an expeditious manner and, thus, allow prompt implementation and evaluation of promising practices. All applicants are reminded, however, that we cannot guarantee that sufficient funds will be appropriated to permit SAMHSA to fund any applications. Questions regarding the status of the appropriation of funds should be directed to the Grants Management Officer listed under Contacts for Additional Information in this announcement.

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Agency

Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration

Action and Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention, Center for Substance Abuse Treatment, and Center for Mental Health Services announce the availability of Fiscal Year 2003 funds for up to 40 grants for States, U.S. Territories, the District of Columbia, Indian Tribes, and consortia of Indian tribes.

The purpose of this targeted capacity expansion program is to enhance State-level capacity for a coordinated response to mental health and substance abuse service needs in the aftermath of large-scale emergencies (both natural and human-caused). Incident response plans and response infrastructure developed under the grant must include both mental health and substance abuse agencies and must focus on coordinated mental health and substance abuse emergency planning and capacity development activities.

SAMHSA will provide extensive technical assistance to grantees in needs assessment, planning, and development of command and response systems. It is anticipated that guidance materials and a multi-State planning conference will be provided for grantees. In addition, individual State requests for technical assistance will be considered on a case-by-case basis.

Approximately \$4,000,000 will be available for up to 40 awards. Annual awards must be for less than \$100,000 in total costs (direct and indirect). Actual funding levels will depend on the availability of funds.

Awards may be requested for up to 2 years. Annual continuation awards will depend on the availability of funds and progress achieved.

Who Can Apply?

States, Indian Tribes, and consortia of Indian tribes may apply. As defined in the Public Health Service (PHS) Act, the term "State" includes all 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

State mental health and substance abuse authorities must apply in partnership. In States, territories, or tribal governments with administratively separate mental health and substance abuse authorities, a lead agency must be designated for grant purposes.

SAMHSA has limited eligibility to States and Indian tribes, because these governmental units have a mandated oversight role in mental health, substance abuse, and emergency management activities.

Application Kit

SAMHSA's grant application kits include the two-part Announcement (also called the Guidance for Applicants or "GFA") and the blank forms (PHS-5161-1) needed to apply for a grant.

The GFA has two parts:

<u>Part I</u> - Provides information specific to the grant or cooperative agreement and is different for each GFA. **NOTE: This document is Part I.**

Part II - Provides general policies and procedures that apply to most SAMHSA grant and cooperative agreements. The policies in Part II that apply to this program are listed on page 15 of this document under "Special Considerations and Requirements."

You will need to use both Part I and Part II to apply for a SAMHSA grant or cooperative agreement.

To get a complete application kit, including Parts I and II, you can:

- Call the Center for Mental Health Services (CMHS) Knowledge Exchange Network (KEN) at 800-789-2647; or
- Download the application kit from the SAMHSA web site at www.SAMHSA.gov. Be sure to download both parts of the GFA.

Where to Send the Application

Send the original and two (2) copies of your grant application to:

SAMHSA Programs

Center for Scientific Review

National Institutes of Health Suite 1040 6701 Rockledge Drive MSC-7710 Bethesda, MD 20892-7710 NOTE: Change the zip code to 20817 if you use express mail or courier service.

Please note:

- 1) Be sure to type: SM 03-001 "State Emergency Response Capacity" in Item Number 10 on the face page of the application form.
- 2) If you require a phone number for delivery, you may use (301) 435-0715.
- 3) All applications MUST be sent via a recognized commercial or governmental carrier. Hand-carried applications will not be accepted.

Application Dates

Your application must be <u>received</u> by October 22, 2002.

Applications received after this date must have a proof-of-mailing date from the carrier before October 15, 2002.

Private metered postmarks are <u>not</u> acceptable as proof of timely mailing. Late applications will be returned without review.

How to Get Help

For questions on program issues, contact:

Seth Hassett, M.S.W. Public Health Advisor 5600 Fishers Lane. Room 17C-20 Rockville, MD 20857 (301) 443-4735

E-mail: shassett@samhsa.gov

For questions on <u>grants management</u> <u>issues</u>, contact:

Stephen Hudak, Grants Management Officer Division of Grants Management Substance Abuse and Mental Health Services Administration 5600 Fishers Lane, Room 13-603 Rockville, MD 20857 (301) 443-9666

E-mail: shudak@samhsa.gov

Funding Criteria

Decisions to fund a grant are based on:

- 1. The strengths and weaknesses of the application, as shown by the review committee;
- 2. Balanced distribution of funds across regions of the country and balanced representation of approved applications from all eligible applicants; and
- 3. Availability of funds.

Post-award Requirements

- 1. Grantees will develop and test comprehensive "All Hazards" response plans.
- 2. Grantees will participate in a multi-State grantee planning meeting that will be conducted by SAMHSA shortly after

- grants are awarded. Representatives from the State mental health and substance abuse authorities will participate in this meeting, which will be funded and organized by SAMHSA.
- 3. Grantees must provide information needed by SAMHSA to comply with Government Performance and Results Act (GPRA) reporting requirements. It is anticipated that a separate contract will be issued for process evaluation of the grants and that this contract will track progress in addressing GPRA measures. The final GPRA measures have not been determined for this program, but it is anticipated that the GPRA measures for the grants will include the following:
 - Number of States with comprehensive "All Hazard" plans;
 - Comprehensiveness of agency linkages, representation, and collaboration in developing and implementing planning and response strategies and infrastructure (e.g., linkages to State Emergency Management agencies, health agencies, victim advocacy groups, and other community stakeholder groups); and
 - Number of grantees with a plan for sustaining mental health and substance abuse emergency response systems.

Once grants have been awarded, SAMHSA staff will consult with grantees regarding final data elements and any necessary clearances for data collection.

Applicants must agree to participate in SAMHSA-sponsored evaluation efforts, which will track the comprehensiveness of "All Hazards" plans, and to seek exemplary plans that have been tested and are operationally feasible. Any evaluation activities will be conducted at no cost to the grantees. Grantees will be expected to provide copies of planning documents, participate in process evaluation interviews, and provide information on challenges or lessons learned from the planning and infrastructure development process.

Grantees must inform the Project Officer of any publications based on the grant project.

Program Overview

In November of 2001, the Substance Abuse and Mental Health Services Administration (SAMHSA) hosted a national summit focusing on mental health and substance abuse needs in the aftermath of the September 11 terrorist attacks. The summit was designed to stimulate increased planning and preparedness activities focusing on mental health and substance abuse issues in disasters and terrorist events at the State and local government levels. See Appendix D for a copy of the planning workbook provided to States at the national summit. This program builds upon the activities initiated during this summit and promotes readiness for all types of crisis events from natural disasters to terrorism.

The mental health and substance abuse aspects of crisis events are most effectively

addressed when comprehensive emergency response plans are in place and community providers are prepared to respond within a larger incident command system prior to the actual event.

Significant mental health and substance abuse resources may be available for response and recovery activities in many types of large-scale crises. Among the resources that may be available <u>after</u> emergencies are the following:

- The FEMA/CMHS Crisis Counseling Assistance and Training Program, which is authorized under the Robert T. Stafford Disaster Assistance Act and jointly administered by the Federal Emergency Management Agency (FEMA) and the Center for Mental Health Services (CMHS). Since 1974, crisis counseling grants have been available to States responding to Presidentially-declared disasters. See Appendix B for a description of this program.
- Under new SAMHSA emergency response authorities, public entities may be eligible for funding when responding to mental health and substance abuse emergency needs not addressed through any other Federal, State, or private resource. Substantial State review and quality control is required for this program. See Appendix C for the Interim Final Rule for this program.

While valuable Federal program resources exist to support response efforts in various types of large-scale events, new resources through this program will help State governments prepare for and develop effective mental health and substance abuse response systems before emergencies happen. States often face challenges in response efforts due to limited disaster mental health and/or substance abuse planning and preparedness at the State and community service levels. Resources focusing on substance abuse issues in disasters are particularly limited.

Incident response strategies developed under this grant program will include both mental health and substance abuse agencies and must focus on coordinated mental health and substance abuse planning and capacity development activities.

Prior to September 11, 2001, most Presidentially-declared disasters had been natural disasters such as tornados, hurricanes, floods, and earthquakes. States and communities had very limited experience developing or implementing plans to address large-scale terrorist events. Very few States had developed formal plans to address unusual threats such as bioterrorist incidents, which may have significant behavioral health consequences. In the wake of September 11, 2001, State mental health and substance abuse authorities must be prepared to play a leadership role in responding to behavioral health needs resulting from large-scale emergencies.

The new grants for State Capacity for Emergency Mental Health and Substance Abuse Response will assure comprehensive preparation activities based on an "All Hazards" planning approach. All Hazards planning has become the standard approach for State Emergency Management Agencies. It includes the development of a core emergency response infrastructure that is adaptable to a wide variety of potential emergencies, as well as contingency plans for unique types of disasters ranging from natural disasters to large-scale terrorist incidents.

All Hazards planning includes an assessment of potential emergency needs and the development of comprehensive plans that include plans for administrative leadership, continuity of operations, communications, public information, and resource management to address specific needs of various emergencies. It is an expectation of this grant program that State plans for mental health and substance abuse services will be tailored to fit within the existing emergency management structure of the State.

As part of the application process, States will review existing plans and conduct needs assessment activities to identify planning gaps; areas in which increased coordination is needed between mental health, substance abuse, and emergency management agencies; and areas in which existing State, county, and city-level incident command systems can be improved to anticipate a comprehensive range of possible issues and needs.

It is expected that State mental health and substance abuse agencies will work jointly to develop the application and that representatives of these agencies will meet with other major agencies that will participate in the All Hazards planning process to agree on a planning approach and identify a lead agency and project director

for grant purposes. This planning process will be continued through ongoing needs assessments and planning once grants have been awarded.

The central goal of this grant program is to help mental health and substance abuse agencies develop coordinated response protocols specifically tailored to unique needs associated with a wide range of potential hazards within their jurisdictions. Incident command systems will be replicated and maintained at the local government level as appropriate. State-to-State information sharing and technical assistance will be fostered through SAMHSA. It is the intent of the program that States, territories, and tribal governments will develop, implement, and monitor coordinated and sustainable plans to maintain incident command and response systems after grants are completed.

Detailed Information on What to Include in Your Application

In order for your application to be **complete**, it must include the following in the order listed. Check off areas as you complete them for your application.

□ 1. FACE PAGE

Use Standard Form 424, which is part of the PHS 5161-1. See Appendix A in Part II of the GFA for instructions. In signing the face page of the application, you are agreeing that the information is accurate and complete.

□ 2. ABSTRACT

Your total abstract should not be longer than 35 lines. In the <u>first 5 lines or less</u> of your abstract, write a summary of your project that can be used in publications, reports to Congress, or press releases, if your project is funded.

□ 3. TABLE OF CONTENTS

Include page numbers for each major section of your application and for each appendix.

□ 4. BUDGET FORM

Use Standard Form 424A, which is part of the PHS-5161-1. Fill out sections B, C, and E of the Standard Form 424A. Follow instructions in Appendix B of Part II of the GFA.

□ <u>5. PROJECT NARRATIVE</u> AND SUPPORTING DOCUMENTATION

The **Project Narrative** describes your project. It consists of Sections A through C. These sections may not be longer than 25 pages. More detailed information about Sections A through C follows #10 of this checklist.

- ☐ Section A Assessment of Current Mental Health and Substance Abuse Emergency Response Capacity and Planning Needs
- □ **Section B** Work Plan for Joint Planning and Infrastructure Development Activities
- □ **Section C** Organizational and Staffing Plan

Supporting documentation for your application should be provided in sections D through G. There are no page limits for these sections, except for Section F (Biographical Sketches/Job Descriptions).

- □ **Section D** Literature Citations. This section must contain complete citations, including titles and all authors, for any literature you cite in your application.
- □ **Section E** Budget Justification, Existing Resources, Other Support

You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project.

- ☐ **Section F** Biographical Sketches and Job Descriptions
 - -- Include a biographical sketch for the project director and for other key positions. Each sketch should be no longer than **two pages**. If the person has not been hired, include a letter of commitment from him/her with his/her sketch.
 - -- Include job descriptions for key personnel. They should be no longer than **one page**.

Note: Sample sketches and job descriptions are listed in Item 6 in the Program Narrative section of the PHS-5161-1.

□ **Section G** – Confidentiality and SAMHSA Participant Protection (SPP)

The seven areas you need to address in this section are outlined after the Project Narrative description in this document.

□ 6. APPENDICES 1 THROUGH 5

- Use only the appendices listed below.
- **Do not** use appendices to extend or replace any of the sections of the Program Narrative unless specifically required in this GFA. (Reviewers will not consider them if you do.)
- **Do not** use more than 40 **pages** for the appendices.

Appendix 1: Copy of Current State Disaster Mental Health Plans

Appendix 2: Copy of Current State Disaster Substance Abuse Plans (if developed)

Appendix 3: Data Collection Instruments and Protocols (if applicable)

Appendix 4: Sample Consent Forms (if applicable). See SAMHSA Confidentiality and Participant Protection section, page 12.

Appendix 5: Letters of Support

□ 7. ASSURANCES

Non-construction Programs. Use Standard form 424B found in PHS-5161-1.

□ 8. CERTIFICATIONS

Use the "Certifications" forms, which can be found in PHS-5161-1.

□ 9. <u>DISCLOSURE OF LOBBYING</u> ACTIVITIES

Use Standard From LLL (and SF-LLL-A, if needed), which can be found in PHS-5161-1. Part II of the GFA also includes information on lobbying prohibitions.

□ 10. CHECKLIST

See Appendix C in Part II of the GFA for instructions.

Project Narrative/Review Criteria – Sections A Through C Detailed

Sections A through C are the Project Narrative/Review Criteria of your application. They describe what you intend to do with your project. Below you will find detailed information on how to respond to Sections A through C. The combined total of pages for these sections cannot exceed 25.

- Your application will be reviewed against the requirements described below for Sections A through C.
- A review committee will assign a point value to your application, based on how well you address each of these sections.
- The number of points after each main heading shows the **maximum number of points** a review committee may assign to that category.
- Bullet statements do not have points assigned to them; they are provided to invite attention to important areas within the criterion.

 Reviewers will also be looking for evidence of cultural competence in each section of the Project Narrative.
 Applications will be assessed on the cultural competency aspects of the review criteria. SAMHSA's guidelines for cultural competence are included in Appendix D in Part II of the GFA.

Section A: Assessment of Current Mental Health and Substance Abuse Emergency Response Capacity and Planning Needs (20 points)

- ▶ Briefly describe the current infrastructure and capacity for emergency and disaster response activities within both the State Mental Health Authority and Substance Abuse Authority. Include a description of structural components, including, but not limited to, the following: any dedicated staff time, any routine preparedness or training activities, organizational roles and responsibilities, and system organization charts (if available) depicting relationships and priority areas for emergency response.
- ► Identify, outline, and discuss both the State mental health and substance abuse authorities' primary areas of responsibility during large-scale emergencies, including the mission, authority, and responsibilities.
- Assess the degree to which Statewide mental health and substance abuse response capacity is either adequate or in need of enhancement. Describe any major limitations or challenges related to emergency and disaster response within both the State Mental Health Authority

and the State Substance Abuse Authority, including staffing limitations, limits to statutory authorities, organizational imperatives, or budget constraints that limit current response capacity.

Note: Applicants may use matrix charts and/or logic model depictions to illustrate the current elements, linkages, lines of communication, coordination mechanisms, responsibilities, and authorities, as well as areas where potential improvements or attention are needed.

Section B: Work Plan for Joint Planning and Infrastructure Development Activities **(60 points)**

- Identify, describe, and discuss the goals, objectives, and activities necessary for planning, system linkage, resource leveraging, and infrastructure development that can be accomplished over the grant period.
- ► Provide a work plan that describes in detail the processes and milestones for developing plans and incident response systems involving mental health and substance abuse agencies. For example, applicants may describe activities that have taken place in pre-planning and application development, the ongoing process of developing or refining plans, proposed exercises or testing of plans, and the time lines for implementation. Allowable activities under these capacity expansion grants will include meetings, personnel, and materials directly related to developing and testing comprehensive response plans, response cadres, and incident response structures. A key expectation will be that applicants will

- develop a plan to leverage resources and/or obtain support to ensure continuation of the activities at the end of the period of Federal funding.
- ➤ Describe the proposed process for coordination with and linkage to the State Emergency Management Agency. Applicants are encouraged to include letters of support from State Emergency Management.
- ► Describe the process for involving key State-level stakeholder groups in the planning and infrastructure development activities. Examples of key stakeholders at the State level include existing State mental health and substance abuse planning groups, State health authorities, law enforcement agencies, victim assistance organizations, political leaders, and State-level advocacy groups. Applicants are encouraged to include letters of support from these organizations or individuals.
- ▶ Describe the process for linking Statelevel planning and infrastructure development to regional, county, and community-based mental health and substance abuse organizations and their representatives.
- ➤ Describe the process for obtaining input and involving a diverse array of cultural and community groups in planning and infrastructure development activities.
- ► Include a description of how public and private sectors, e.g., service providers, businesses, faith communities, primary care professionals, and other stakeholder groups can contribute to the development

of infrastructure capacity. Applications will be reviewed to ensure extensive community level and private sector input in proposed planning efforts.

► Describe a process for ensuring input and involvement from representative groups of potential service recipients, including mental health consumers and their families, as outlined in the CMHS Guidelines for Consumer and Family Participation (Appendix A).

Section C: Organizational and Staffing Plan (20 points)

- Describe the organizational structure, lines of supervision, and management oversight for the project. Specifically, describe the plans for partnership between mental health and substance abuse authorities and proposed protocols for ongoing communications and joint planning activities. Identify the lead State agency for purposes of administering the grant, and describe the rationale for selecting this agency as the applicant.
- Describe the qualifications and roles of key personnel.
- Provide an organizational chart showing the organizational placement of key personnel involved in the project. The applicant may also provide other visual diagrams showing key organizational components involved in planning efforts and the structure for involvement of organizational leadership.
- Describe the facilities and equipment that will be used to implement the

proposed work plan. Indicate which facilities and equipment will be provided by the applicant organization and which will be purchased or leased under the grant. Descriptions should be consistent with information provided in the budget and budget narrative. Indicate if the facilities will be compliant with the requirements of the Americans with Disabilities Act (ADA).

NOTE: Although the **budget** for the proposed project is not a review criterion, the Review Group will be asked to comment on the budget appropriateness after the merits of the application have been considered.

CONFIDENTIALITY AND SAMHSA PARTICIPANT PROTECTION

You <u>must</u> address seven (7) areas regarding SAMHSA participant protection in your supporting documentation. If one or all of the seven (7) areas are not relevant to your project, you must document the reasons. No points will be assigned to this section.

This information will:

- 1. Reveal if the protection of participants is adequate, or whether more protection is needed.
- 2. Be considered when making funding decisions. SAMHSA will place restrictions on use of funds until all participant protection issues are resolved.

Some projects may expose people to risks in many different ways. In the Confidentiality/Participant Protection Section of your application, you will need to:

- Report any possible risks for people in your project.
- State how you plan to protect them from those risks.
- Discuss how each type of risk will be dealt with, or why it does not apply to the project.

The following seven (7) issues <u>must be</u> <u>discussed</u>:

Protection of Clients and Staff from Potential Risks

- Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse affects.
- Discuss risks that are due either to participation in the project itself, or to the evaluation activities.
- Describe the procedures that will be followed to minimize the effects of or protect participants against potential risks, including risks to confidentiality.
- Give plans to provide help if there are adverse effects on participants.
- Describe alternative treatments and procedures that may be beneficial to the subjects, where appropriate. If you decide not to use these other beneficial

treatments, provide reasons.

2 Fair Selection of Participants

- Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background. Address other important factors, such as homeless youth, foster children, children of substance abusers, pregnant women, or other special population groups.
- Explain the reasons for using special types of participants, such as pregnant women, children, people with mental disabilities, people in institutions, prisoners, or people likely to be vulnerable to HIV/AIDS.
- Explain the reasons for <u>including or</u> excluding participants.
- Explain how you will recruit and select participants. Identify who will select participants.

3 Absence of Coercion

- Explain if participation in the project is voluntary or required. Identify possible reasons why it is required (e.g., court orders requiring people to participate in a program).
- State how participants will be awarded money or gifts, if you plan to pay them.
- State how volunteer participants will be told that they may receive services and incentives, even if they do not complete the study.

Data Collection

- Identify from whom you will collect data (e.g., participants themselves, family members, teachers, or others). Explain how you will collect data and list the site. For example, will you use school records, interviews, psychological assessments, observation, questionnaires, or other sources?
- Identify what, if any, type of specimen (e.g., urine, blood) will be used. State if the material will be used just for evaluation and research, or for other uses. Also, if needed, describe how the material will be monitored to ensure the safety of participants.
- Provide in Appendix 3, titled "Data Collection Instruments/Interview Protocols," copies of <u>all</u> available data collection instruments and interview protocols that you plan to use.

6 Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.
- Describe:
 - How you will use data collection instruments.
 - Where data will be stored.
 - Who will or will not have access to information.
 - How the identity of participants will be kept private (e.g., using a coding system on data records, limiting access to records, or storing identifiers separately from data).

NOTE: If applicable, grantees must agree to

maintain the confidentiality of alcohol and drug abuse client records, according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

6 Adequate Consent Procedures

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Include how the data will be used and how you will keep the data private.
- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

NOTE: If the project poses potential physical, medical, psychological, legal, social or other risks, you should get <u>written</u> informed consent.

Indicate whether you will get informed consent from participants, or from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

• Include sample consent forms in your Appendix 4, titled "Sample Consent Forms." If needed, provide English translations.

NOTE: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from

liability for negligence.

• Describe whether separate consents will be obtained for different stages or parts of the project. For example: Will they be needed for both the treatment intervention and the collection of data? Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7 Risk/Benefit Discussion

Discuss why the risks are reasonable when compared with expected benefits and importance of the knowledge from the project.

Special Considerations and Requirements

SAMHSA's policies and special considerations and requirements related to this program can be found in **Part II** of the GFA in the sections by the same names. The policies, special considerations, and requirements related to this program are:

- Population Inclusion Requirement.
- Government Performance Monitoring.
- Healthy People 2010 focus areas related to this program are in Chapter 26: Substance Abuse and Chapter 18: Mental Health and Mental Disorders.
- Consumer Bill of Rights.
- Promoting Nonuse of Tobacco.
- Single State Agency (SSA) Coordination.
- Intergovernmental Review (E.O. 12372).
- Confidentiality/SAMHSA Participant Protection.